

## EFFECTS OF CONNECTIVE TISSUE MANIPULATION IN PRIMARY DYSMENORRHEA: A RANDOMIZED CONTROLLED TRIAL

### Hypothesis / aims of study

Primary dysmenorrhea (PD) is a common gynecological problem in women of childbearing age. It is defined as the cramps or lower abdominal pain that precede or accompany menstruation, in the absence of any organic pathology. The therapeutic options for the treatment of dysmenorrhea are few and not totally effective (1). Connective tissue manipulation (CTM), a manual reflex therapy, targets the superficial connective tissues to stimulate segmental and suprasedgmental autonomic cutaneovisceral reflexes in order to restore autonomic balance and reduce dysfunction. In PD, it can be used to increase circulation to the uterus, reducing congestion and menstrual pain (2). There is insufficient evidence to state whether CTM is an effective treatment for the PD (3). Therefore, the aim of this randomized controlled study was to investigate the effects of CTM in women suffering from PD.

### Study design, materials and methods

This was a prospective, assessor-blind randomized controlled trial. All participants were suffering from PD, defined as the presence of a menstrual pain intensity above 4 on a 0-10 cm visual analog scale (VAS) anchored at 0=no pain and 10=unbearable pain. Inclusion criteria were nulliparous women over 18 years of age and with regular menstrual cycle (28-34 days). Patients who had other chronic pain syndromes, psychiatric disorder, oral-contraceptive or antidepressant use, intra-uterine device and previous gynecological interventions were excluded. Subjects were randomly assigned to the intervention group (n=15) or the control group (n=15), using a computer generated block randomization procedure with block of four. The intervention group received CTM in addition to the lifestyle advice, while the control group was given only lifestyle advice.

Primary outcome measure was the pain intensity score on the first day of menstruation assessed by 10-cm VAS. Secondary outcome measures included the average pain intensity in the first three days of menstruation, the number of analgesics taken in the last menstruation and menstrual attitude score by Menstrual Attitude Questionnaire (MAQ). State-Trait Anxiety Inventory (STAI) was applied only at baseline to evaluate subjects' emotional mood. In CTM; sacral, lumbar, lower thoracic (figure 1) and anterior pelvic regions (figure 2) were manipulated five days per week, from the estimated day of ovulation (formula: cycle length in days -14) until the next period begins. All assessments were repeated at the end of the treatment with the same protocol by an assessor blinded to group allocation. The other researcher not having any role in the treatment also evaluated the patients' satisfaction with CTM with two questions on a rating scale of 0-10 (Q1: How satisfied were you with the overall treatment you received?, Q2: Would you recommend this treatment to someone you know who has a dysmenorrhea problem?). Descriptive statistics of variables were presented as means and standard deviations (SDs) or as medians and interquartile ranges (IQRs). Differences between groups were analysed with Mann-Whitney U test (non-normally distributed data). Alpha was set at 0.05.

### Results

30 women of mean age 21.7 (SD: 2.2) years were enrolled in the study. Of these patients, 15 were in CTM group, 15 were in control group. There were no statistically significant differences between two study groups at baseline in demographic characteristics (age, body mass index, pain duration, pain intensity during last 6-month and STAI score) or outcome measures ( $p > 0.05$ ). The number of CTM sessions ranged from 10 to 15.

According to Mann-Whitney U test for the primary outcome, a total sample size of 30 achieves 99.0 % power to detect an average 4 points difference between groups in VAS score with a significance level of 0.05. Compared with controls, CTM group showed a statistically significant improvement in pain intensity on day-1 (Table 1). All participants (100%) in CTM group reported improvement in pain intensity score. None of the participants reported cure (zero at VAS).

The between-group comparison showed also a decrease in average pain intensity, number of analgesics and an improvement in MAQ score-III ("menstruation as a natural event" subscale) ( $p < 0.05$ ) (Table 1). There were no intergroup differences for other subscales of MAQ.

In CTM group, patients reported high satisfaction scores with treatment determined by the 0-10 rating scale (mean±SD: 7.4±1.4 and 8.0±1.4 for Q1 and Q2, respectively).

### Interpretation of results

This was the first randomized controlled trial about the effects of CTM in PD. According to the results of the present study, patients with PD showed a greater improvement in menstrual pain intensity and more reduction in the amount of analgesics received during the last menstruation compared to control group. The lack of differences in some subscales of MAQ may be attributed to the treatment duration and short-term effects of CTM. We think that long-term follow-up is needed to see significant changes in the menstrual attitude of dysmenorrheic patients.

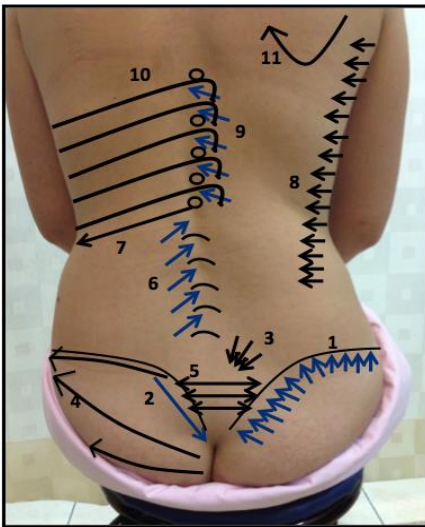
### Concluding message

CTM is an effective physiotherapy approach for relieving menstrual pain in the short-term in women with PD. A higher number of cycles of therapy is needed to determine whether the cure is possible with CTM. Long-term follow up will also clarify the sustainability of effects of CTM.

**Table 1.** Comparison of changes between CTM and control groups

Variables	CTM group		p
	$\Delta 1$ (median, IQR)	$\Delta 2$ (median, IQR)	
Pain intensity- (day 1) (cm)	4.4 (2.6-4.8)	-0.2 (-0.3--0.1)	<b>0.001*</b>
Average pain intensity (of the day 1,2 and 3) (cm)	2.8 (1.6-4.0)	-0.2 (-0.3--0.1)	<b>0.001*</b>
Number of analgesics	1.0 (1.0-2.0)	0.0 (-1.0-1.0)	<b>0.001*</b>
MAQ-I score	0.0 (-2.0-2.0)	1.0 (0.0-2.0)	0.390
MAQ-II score	1.0 (-2.0-2.0)	-1.0 (-1.0-3.0)	0.802
MAQ-III score	2.0 (1.0-3.0)	-2.0 (-3.0-1.0)	<b>0.023*</b>
MAQ-IV score	-1.0 (-2.0-2.0)	0.0 (-3.0-2.0)	0.770
MAQ-V score	1.0 (-2.0-2.0)	0.0 (-2.0-1.0)	0.147

CTM: Connective tissue manipulation, IQR: Interquartile range,  $\Delta 1$ ,  $\Delta 2$ : Differences between baseline and last visit, MAQ-I, II, III, IV, V: subscale scores of Menstrual Attitude Questionnaire, p: Comparison of changes ( $\Delta 1$  and  $\Delta 2$ ) between CTM and control group, Mann-Whitney U test, \*  $p < 0.05$ .



**Figure 1.** Directions of connective tissue manipulations applied over the sacral, lumbar and lower thoracic regions



**Figure 2.** Directions of connective tissue manipulations on anterior pelvic region

#### References

1. Harel, Z. (2008) Dysmenorrhea in adolescents and young adults: from pathophysiology to pharmacological treatments and management strategies. Expert opinion on pharmacotherapy, 9 (15), 2661-2672.
2. Holey, L.A., Dixon, J. (2014) Connective tissue manipulation: a review of theory and clinical evidence. Journal of bodywork and movement therapies, 18 (1), 112-118.
3. Goats, G.C. (1994) Massage--the scientific basis of an ancient art: Part 2. Physiological and therapeutic effects. British journal of sports medicine, 28 (3), 153-156.

#### Disclosures

**Funding:** No **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov; NCT02372123 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Hacettepe University, Ethics Boards and Commissions, Decision no: GO 15/98-24 **Helsinki:** Yes **Informed Consent:** Yes